Section 7 Performance Assessment[1]

Comment Issues Page #

Issue A: Is EPA's requirement that NRC use the mean or median of the highest results for compliance determinations appropriate?

1. While EPA's reasoning is sound, the choice of mean or median is an implementation detail that should be left to NRC. (229, 236, 616)

2. I fear that by using the mean that an RMEI by an individual of the CG may be diluted by assuming a large population of lesser exposed RMEI's. NO don't use the mean. Do like is common in current EIS practice and prepare for the worst case exposures. (168)

3. The EPA should use an approach of specifying that the dose limit to the critical group limit should be the 99 percent upper confidence bound, based on those parameters that can be quantified. (288)

4. [R]eliance on the mean of the distribution of highest dose is not justified. The performance assessment must address the dose to the maximally exposed individual(s), including the conditions

[1] All acronyms are defined in Appendix B.

of age and physical conditions of the dose recipients. The doses to other members of the exposed population must also be incorporated into the standards. (370)

5. This appears to be a reasonable approach that has more basis in scientific precedent than the "expected dose" used by DOE. (386) Given the uncertainties inherent in performance assessment, compliance should be based on consideration of the full range of values. Either the mean or median of the distribution of the highest doses from various exposure scenarios should adequately address uncertainties associated with performance-assessment results, depending on the degree of skewness. (570)

6. The ICRP approach is to favor a presentation of the results as ranges of numbers or bounding estimates and to emphasize the inherent judgement necessary in evaluating whether there is compliance with the constraints in compliment to the compliance with technical managerial principles. (515)

7. DOE believes that using the mean or median is an acceptable and conservative measure... DOE believes that the uncertainties in performance assessment are best addressed by consideration of the full range of values during the licensing process. The implementing regulator should be allowed to decide, considering this full range, whether there is sufficient confidence that the mean or expected value meets the standard. (629)

8. We support EPA's choice of the mean of the distribution of the highest doses resulting from the performance assessment as the appropriate comparison with the all-pathways, individual-protection radiation standard. However, we consider that any confidence limits and uncertainties applied to this approach should be left to the NRC to determine through implementation of the EPA's standard. (777)

Response to Issue A:

EPA has specified a compliance measure we believe is reasonable but still conservative, i.e., the mean of the distribution of projected doses from DOE's performance assessments. We believe that specifying this compliance measure is necessary to provide the appropriate context for implementation of the standard. Supplying context for understanding the intent of the standard is necessary to constrain and direct the otherwise unbounded range of approaches to demonstrating compliance that could be justified in the absence of such context. For example, if only an exposure limit was specified in the standard, rather than the mean of a distribution of calculated dose assessments, it is possible that a small number of assessments could be used to demonstrate compliance. In such a case, the full range of relevant site conditions and processes would not be considered and the uncertainties in projecting long-term performance would not be captured by the analyses and the regulatory decision making. At the other extreme, without a defined performance measure, endless and exhaustive site characterization studies and analyses could be required, driven by a perceived need to identify the most extreme "worst-case" scenarios. We believe that a thorough assessment of repository performance expectations should examine the full range of reasonably foreseeable site conditions and relevant processes expected during the

regulatory time frame. In making quantitative estimates of repository performance, we believe that unrealistic or extreme situations or assumptions should not dominate estimates of expected performance. With these considerations in mind, we believe that specifying a performance measure is necessary to supply a requisite context for implementing the rule in the regulatory process as well as providing the applicant (DOE) a focus for its efforts to build the compliance arguments and supporting calculations.

EPA believes that a probabilistic approach to repository performance assessments would appropriately capture the range of anticipated site conditions and relevant features, events, and processes. Probabilistic analytical methods are well established in the repository performance assessment field [DEIS (DOE/EIS-0250D) and Viability Assessment (DOE/RW-0508), Docket A-95-12, Items V-A-4 and V-A-5)] and we believe they will be used to project repository performance over the long time frames involved to assess the range of variations in dose that can be expected. We have been reluctant to explicitly specify that a probabilistic approach must be used because such statements could be interpreted to bar the use of deterministic analyses in any sense, which is also not our intent. We recognize that deterministic analyses can be useful for carefully constructed bounding analyses and sensitivity studies and we do not intend to restrain such constructive applications. However, we do require that DOE demonstrate compliance with the individual-protection standard by means of performance assessment, and we have revised the definition of performance assessment to incorporate probabilistic considerations. In addition, by specifying the mean as the performance measure, we are unmistakably implying that a sufficiently large number of performance projections should be made for the repository to consider the full range of conditions and processes, and also are implying that a probabilistic approach should be used to give a relative weighting to the results of these assessments. Given a large number of performance projections, the mean of the distribution will less likely be overwhelmed by unlikely, extreme results.

In line with EPA's use of the term "reasonable expectation," the fundamental compliance measure consistent with a literal interpretation of this term would be the mean value of the distribution of calculated doses. As the only alternative for a compliance measure, the mean may be interpreted too restrictively, however. In actuality, some situations may result in very high dose estimates for situations that have low probabilities and simply averaging these "outliers" into the distribution of calculated dose estimates can bias the mean to perhaps unrealistically high levels. Although this is certainly a conservative approach, which is desirable, the effects can be overly conservative resulting in driving regulatory decision making on the basis of very low probability and potentially unrealistic situations. Another interpretation of the "expected" situation would involve using the median of the expected range of calculated values. The median (reflecting a value exceeded half of the time) may be more representative of actual conditions, since it is reasonable to expect that at least some of the variables involved in the performance calculations have skewed distributions and the resulting distributions for all the situations assessed would show a non-uniform distribution. If the parameter value distributions for those variables that strongly influence the repository performance are skewed, either toward higher or lower values, the median of the distribution of calculated doses could be either higher or lower than the arithmetic mean. Although we proposed using the higher of the mean or median, after further consideration we

believe that the mean alone will be an appropriate measure of compliance. We believe this approach is sufficiently conservative in that it leans toward giving greater weight to calculations that result in higher exposures, without being overly influenced by "worst-case" and possibly extreme low-probability situations.

Many comments supported the mean or median selection (229, 236, 386, 570, 616, 629, 777), particularly in consideration of the uncertainties involved in projecting repository performance (570, 629). As some comments stated explicitly, the full range of possible parameter values should be examined in repository performance assessments and in the licensing process (570, 629). EPA agrees with these comments for the reasons explained in the preceding text.

A number of commenters stated that while they agreed with the selection of performance measures, the choice should be left as an implementation detail for NRC (229, 236, 616, 777), while some comments (629, 777) stated that measures of confidence should be left to the implementing authority. With respect to whether this constitutes an implementation function that should be left to NRC, EPA believes that specifying the fundamental compliance measure is necessary as a means to supply the appropriate context for understanding the intent of the rule and for implementation guidance. We do not believe that setting the fundamental compliance measure intrudes on the implementation function. The primary task for the regulatory authority is to examine the performance case put forward by DOE to determine "how much is enough" in terms of the information and analyses presented, i.e., how will the regulatory authority determine when the performance case has been demonstrated with an acceptable level of confidence? We have proposed no specific measures in our standard for that judgement. We have not specified any confidence measures for such judgements or numerical analyses, neither have we prescribed analytical methods that must be used for performance assessments, quality assurance measures that must be applied, statistical measures that define the number or complexity of analyses that should be performed, nor have we proposed any assurance measures in addition to the numerical limits in the standard. We have specified only that the mean of the dose assessments must meet the exposure limit, without specifying any statistical measures for the level of confidence necessary for compliance, such as a 95 or 99% confidence level for the mean. We believe setting a confidence level is clearly an implementation function that should be left to NRC and we have made no requirements in the standard to foreclose NRC's flexibility in setting appropriate confidence measures. In the WIPP certification criteria, where we were also the implementing agency, we did set a confidence measure [§194. 55 (d) and (f)] in addition to the basic performance measure, as was our responsibility. In addition, for the WIPP certification standard we included implementation requirements, including analytical approaches [§194.55(b)] along with quality assurance requirements (§194.22), other assurance requirements (§194.41), requirements for modeling techniques and assumptions (§194.23 and 25), use of peer review and expert judgement (§194.26 and 27). These requirements go well beyond the simple statement of a compliance measure. We have not incorporated a similar level of detail in the Yucca Mountain standard because we believe we must specify only what is necessary to provide the appropriate context for NRC's implementation. We therefore disagree that this choice is an intrusion into the implementation responsibilities of NRC.

Some comments advocated alternative dose limits (168, 288), more specifically that "worst-case" or 99th percentile values of the calculated dose distribution should be used. As explained above EPA believes that the mean will reflect the effects of high dose situations sufficiently and we do not feel the alternatives proposed are compatible with our approach. As we have explained in the response to comments on our "reasonable expectation" approach, the intent of reasonable expectation is to fully understand and appreciate the inherent uncertainties involved in projecting repository performance to engage in regulatory decision making with a full understanding of all the uncertainties. We believe that under this approach, high dose situations will be identified and described, particularly their probabilities, and such situations will be carefully examined in the licensing process to determine their underlying assumptions so that decisions are not driven by unrealistic, or very low probability situations. We believe that the reasonable expectation approach, in combination with the performance measures we have specified and the necessary implementation by NRC, will assure that the full range of potential repository performance will be evaluated appropriately.

One comment (370) stated that the dose to the maximally exposed individual (further qualified by age and other physical conditions) should be the performance measure and that doses to other individuals should be incorporated into the standard. EPA believes our selection of dose receptor (the reasonably maximally exposed individual) is a conservative but reasonable approach consistent with our approach to regulatory decisions in general. In the standard we have specified that certain characteristics of the dose receptor should be based on characteristics of the current population (§197.21) so that the receptor is representative of the exposed population (which will weigh the extreme physical conditions in proportion to their actual occurrence in the population). We believe that postulating receptors with maximum "worst-case" characteristics is an arbitrary and fundamentally speculative approach that makes regulatory decision making difficult because the choices cannot be clearly justified, i.e., one speculative choice is no more defensible than another in terms of decision making. In this regard we are consistent with the position of NAS, which stated that it would be reasonable to "protect the vast majority of members of the public" rather than focusing on "the risks imposed on a very small number with unusual habits or sensitivities" (NAS Report, p. 51-52).

One comment described the ICRP approach as an alternative to EPA's selection of performance measures (515). We believe that the applicant's compliance case will document the full range of performance projections and consequent dose assessments consistent with the intent of the comment. As we have explained in our discussions of the "reasonable expectation" approach, the full range of uncertainties should be identified and taken into consideration in regulatory decision making. We believe our general approach and performance measures will provide the information and insight advocated by this comment.

EPA notes that for the WIPP certification, the compliance measure that we used for the individual protection standard was the higher of the mean or median of the calculated distributions of doses from releases [§194.55(f)]. We proposed the same performance measure as appropriate for the Yucca Mountain repository so that an equivalent measure would be applied in both geologic repository situations. We have reviewed information and assessments done for the Yucca

Mountain site [such as those in the DEIS (DOE/EIS-0250D) and Viability Assessment (DOE/RW-0508), Docket A-95-12, Items V-A-4 and V-A-5] and have not found evidence that uncertainties and technical difficulties in assessing performance for the site are dramatically greater than at the WIPP site – to the extent that a very different compliance measure is justified, although the respective sites have their unique differences and uncertainties. However, in our final rule we are specifying the mean alone as the basic compliance measure. Projecting repository performance at either site presents technical difficulties and uncertainties that require detailed site characterization studies and encourage the use of probabilistic approaches to dose assessments. In the BID for the WIPP rule (EPA 402-R-96-002, Docket A-95-12, Item V-A-23), the use of the mean as a conservative but reasonable measure of repository performance is discussed in detail. The WIPP BID contains a more statistically oriented discussion of compliance measures and confidence measures. The mean or median are both reasonably conservative measures because they are influenced by high exposure estimates found when analyzing the full range of site conditions and relevant processes, without being geared to exclusively reflect high-end results, as would be the case if a high-end percentile of the distribution were selected as the measure. As noted in the WIPP BID, the mean and median values of the distribution of calculated doses are the same if the distribution of calculated doses is symmetrically distributed around the mean value, but will differ if the input data used in the calculations shows a prominent skewness either to generally high or low values. Because it is possible to observe skewed parameter distributions, a non-uniform dose distribution is not unexpected. Nevertheless, we believe that use of the mean alone will adequately address these questions.

Issue B: Is EPA's limitation on low-probability features, events, and processes (proposed as §197.40) appropriate?

1. If our interpretation is correct, events with lower than one chance in 10,000 chance of occurring within 10,000 years means an annual occurrence rate of less than one in 100 million (10-8) per year. No rationale for this choice is presented. This is another implementation area that should be left to NRC. (328)

2. EPA should examine unplanned release scenarios of low probability to determine if the Yucca Mountain Repository should operate. (416) EPA should propose a "design standard" for the Yucca Mountain Repository. (414)

3. It is unclear: (1) Whether performance assessments for ground water protection (and human intrusion) exclude additional natural events and processes compared to that for the individual protection standard, and (2) What the extent of the additional exclusion is. DOE recommends that EPA clarify the exclusion of unlikely or very unlikely events and processes. (650)

4. We support EPA's position on allowing the exclusion of unlikely natural events from both the ground water and human-intrusion scenarios. (767)

5. DOE agrees with EPA's conclusion that the geologic record is best preserved in the relatively recent past. DOE believes that probabilities of processes and events for the 10,000 year period of

compliance should be calculated based on this record because this record is likely to be representative of processes and events for the next 10,000 years. (649)

6. The Quaternary has long been accepted as the appropriate period in the geologic record to use and requires no further action from EPA. (572)

Response to Issue B:

Comment 328 asks for an explanation of the probability cut-off EPA proposed in §197.40 of the standard (§197.36 of the final rule) as it relates to framing performance assessment scenarios for projecting repository releases. The purpose of a performance assessment is to evaluate the performance of the repository under expected conditions, within reasonable variations (please see additional discussions in this document and the preamble to the final standard concerning our "reasonable expectation" approach and performance measures for pertinent information related to this question also). This means that extremely unlikely or speculative features, events, and processes should not play a prominent role in the assessment. There is a certain amount of judgment involved in selecting a specific probability level below which features, events, and processes are considered so "unlikely" that they should not be evaluated. We see the level we selected as the threshold for these "very unlikely" features, events, and processes (a 1 in 10,000 chance of occurring within 10,000 years after disposal, sometimes represented as an annual probability of 10^{-8}) as providing sufficient room for many features, events, and processes that might be considered unlikely but could have a significant impact on the results of the assessment. It is not intended to represent the probability of an event occurring in any particular year (which, as the comment points out, would be vanishingly small), but must be viewed in the context of the probability of a feature, event, or process being active at the site during the next 10,000 years. This level also translates to a 1 in 100 (i.e., 1%) chance of occurrence over 1 million years, the length of time NAS identified as the period of geologic stability, so that DOE's projections beyond 10,000 years may include these less likely features, events, and processes. Nor should it be interpreted to mean that any feature, event, or process that has taken place at the site during the last hundred million years should be included in the repository performance assessments. The repository block tuffs are in the range of 11.4 - 15.2 million years old (BID, Chapter 7). Extending the time frame for examining site conditions back that far brings into consideration features, events, and processes associated with the original deposition of the repository host rocks and some of the surrounding rocks. The inclusion of such features, events, and processes are not likely to be repeated in the next 10,000 years unless convincing arguments can be made for the reoccurrence of the type of volcanic activity that created the repository tuff deposits initially. In contrast, studies of the volcanic history around the site area point to the occurrence of a different type of volcanic activity in the relatively recent geologic past, with some events occurring less than 10,000 years ago. This type of volcanism (basaltic volcanism, exemplified by the Lathrop Wells lava cone and other features in the repository area) appears to be the type that has some probability of occurring within the next ten thousand years (BID, Chapter 7).

Comments 649 and 572 expressed agreement with our assertion that the Quaternary Period is the appropriate portion of the geologic record to use in estimating probabilities for natural features,

events, and processes that may occur at the site over the next 10,000 years. EPA agrees with these comments for the reasons stated above and in the comments. The Quaternary Period contains the best preserved evidence of features, events, and processes that have taken place at the site thereby allowing the most reliable means of estimating their probabilities. It also covers the past glacial periods (in the Pleistocene) where precipitation rates would be higher than today, thereby offering a means of realistically estimating future changes in precipitation rates for use in repository performance assessments. Such variations in climatic and geologic conditions are required (§197.15) so that the repository performance projections will address possible variations in site conditions during the regulatory period (10,000 years) and beyond that time. Climatic changes over the very long-term [the one million year period of "geologic stability" described by NAS (NAS Report, pp. 6 and 91-2)] can produce significant changes in site conditions that would strongly affect repository performance projections by changing important performance factors from precipitation rates over Yucca Mountain to shifts in population downgradient from the repository, as noted in the NAS Report (pp. 91-92).

Comment 416 stated that EPA should examine low probability unplanned release scenarios to determine if the repository "should operate." This comment appears to be assuming that EPA is the regulatory authority with approval responsibilities for the repository. We are charged with framing the standard, but NRC is responsible for the final review and approval process for the repository, i.e., determining if it "should operate." In reviewing the data for site conditions (see Chapters 7 and 8 of the BID) and DOE's most recent assessments of the site's performance in the DEIS and DOE/VA (Docket A-95-12, Items V-A-4 and V-A-5), EPA did not find evidence that low probability features, events, and processes, that could have a potential to result in releases likely to exceed the standard, would be excluded from DOE's assessments of repository performance. For example, the potential for disruption of the repository by volcanic events will be considered since the probability estimates are above the cut-off limits in the standard (Viability Assessment, vol. 3). The effects of seismic activity and the potential for nuclear criticality, the other two important disruptive processes, are also being evaluated by DOE (Viability Assessment, vol. 3). In implementing our standards, NRC has the flexibility to consider features, events and processes with probabilities below our cut-off value (i.e., lower than 10^{-8} probability) if it deems them important to its decision making responsibilities, though not specifically in determining compliance with our standards. We believe our probability cut-off levels will not artificially eliminate important features, events, and processes from the repository assessment efforts and that the final determination of whether the repository should operate, as this comment states, is the responsibility of NRC.

A closely related comment (414) stated that EPA should establish a "design standard" for the repository. The EnPA mandates that EPA promulgate public health and safety standards for protection of the public from releases from radioactive materials stored or disposed of in the repository. The EnPA does not authorize or require us to promulgate a standard tied to a specific repository design. Therefore, we have not taken an approach that would establish requirements for design, or anticipated performance of specific aspects of the repository design. Moreover, a design standard is not practical for a number of reasons. Establishing overarching health-based requirements in the standard allows the repository developers flexibility in developing repository

designs that are capable of meeting the standard's requirements, and to optimize the designs as ongoing site characterization studies reveal more detail about the repository site's natural system. Allowing the repository design to be modified to increase confidence in its projected performance as site information becomes more reliable, up until the time the actual repository license application is submitted, is clearly a desirable approach. Establishing design requirements in advance in the standard seriously limits the flexibility to evolve the repository design to optimize its performance and the confidence that can be placed in performance projections. Prejudging the repository design (i.e., the various components of the engineered barrier system) and the containment and waste isolation functions of elements in the design is not a prudent course, since it could seriously limit design optimization efforts, misdirect attention from the overarching goal of health protection to potentially exposed individuals, and add considerable uncertainty in the licensing process by establishing performance standards that are not directly measures of health protection. In carrying out its implementation responsibilities, if NRC determines that requirements for specific aspects of the repository design are necessary, it can impose such requirements. We believe consideration of design requirements are implementation concerns more properly addressed by NRC (see also the response to comment 486 for a discussion of subsystem performance requirements).

Two comments dealt with the inclusion of unlikely and very unlikely features, events, and processes from the performance assessments to be done for the human intrusion and ground-water protection standards (650 and 767). Comment 650 asked for clarification on the inclusion or exclusion of unlikely features, events, and processes in the ground-water protection and human intrusion standards. Unlikely natural features, events, and processes are excluded from the human intrusion assessment [§197.26(f) and §197.36]. The stylized intrusion scenario is intended to test the repository performance by an assumed by-passing of the engineered barrier and part of the natural barrier (the unsaturated zone below the repository). Combining unlikely features, events, and processes with the stylized intrusion scenario is not reasonable from two perspectives. As discussed in the NAS Report (Chapter 4), the intent of the analysis is to test repository performance under expected conditions, with the hope that the repository will be "resilient" to a limited human intrusion event. EPA agrees with this recommendation, as discussed elsewhere in this document and in the preamble. The inclusion of unlikely features, events, and processes would be counter to that intention of testing the expected "resilience" of the repository, and therefore we have not included in the standard requirements to do so in the performance assessments. NAS also concluded in its report that there was no scientific way to make supportable predictions for the probability of human intrusion to breach the repository barriers. In the light of this conclusion, NAS recommended that an intrusion be assumed to occur and be assessed (NAS Report, Chapter 4). As some comments on human intrusion pointed out (see comment responses on human intrusion in Section 5 of this document), drilling for water from the top of Yucca Mountain rather than in the adjacent valleys is very unlikely and we agree that the actual probability of that event is very low. If we were to combine additional unlikely features, events, and processes with the stylized intrusion scenario (which in reality has a low probability although difficult to define reliably), we would in reality be requiring compliance be met for very unlikely situations (the probability of such situations would be the product of the low probability for the drilling event itself multiplied by the low probability of the added unlikely features, events,

and processes). Such a position is inconsistent with our position on the probability limits for features, events, and processes to be included in repository assessments for the individual protection standard (§197.36).

Regarding the use of low probability unplanned release scenarios, relying on the worst conceivable event without regard to probability would be neither economically nor technically justifiable. In addition, EPA's role is not to "determine if the repository should operate," but to establish a standard that protects human health and the environment in the Yucca Mountain region. The NRC's role is to approve or disapprove the license application. As part of that determination, NRC will evaluate compliance with the EPA standard. The NRC's licensing of nuclear facilities typically requires analysis of accident or "off-normal" events to ensure that the facility's design basis is appropriately identified. The NRC may take into account lower probability events in the broad context of licensing, but not for determining compliance with the EPA standard.

The human intrusion and ground-water standards should apply the same restriction on low-probability ("unlikely") features, events, and processes. EPA has left it to NRC to define the level of probability that constitutes an "unlikely" feature, event, or process. The human intrusion standard assumes that a single borehole penetrates the repository. No probability has been assigned to such an event, which is consistent with the NAS recommendation.

Issue C: Is EPA's requirement for repository performance projections for periods beyond 10,000 years appropriate?

1. Requiring projections for 10,000 and 100,000 years could be confusing to the public and the licensing authority. How should long-term projections be evaluated if they are well above the 10,000 year standard? (473)

2. Even 10,000 year projections involve methodologies that become more difficult to prove with increasing time. (272) Requiring projections beyond 10,000 years invites calculations of increasingly greater uncertainty. (567)

3. A better approach would be to require periodic updates of the performance assessment using better data. This would serve as a check of the original assumptions and increase confidence in the understanding of repository conditions. (557)

4. If EPA is not going to extend the compliance period beyond 10,000 years, there needs to be technically feasible backup licensing criteria that addresses the longer-term waste isolation characteristics of the proposed site after the engineered barriers fail. (486)

5. The text in the preamble (page 46993) should be changed to state that "NRC is not required" to use additional analysis in determining compliance with proposed 197.20. NRC should not be constrained from using post-10K year calculations if it deems such use appropriate. (593)

6. DOE agrees on the statements for the use of the 10K and 100 K performance assessments. (646) If the post-10,000 year assessments are to be used for regulatory insight, it is appropriate, but this should be left up to NRC to consider what weight should be given to such speculation, and EPA should make no requirement. (236)

7. Given that the proposed EPA standard requires that the performance of the disposal system be examined after 10,000 years if the peak dose is calculated to occur then, there may be little practical difference between the TYMS report's recommendations and the proposed EPA standards. The major issue is that EPA provides no guidance on how analyses should be done for the period of geologic stability beyond 10,000 years and gives no indication of how the results should be used in judging acceptability. (398)

Response to Issue C:

This issue relates directly to Question 16 in the preamble in the proposed standard. Although EPA asked for comment on the appropriate use of projections after the regulatory time period, the thinking on this issue depends to a significant extent on our decision to set the regulatory time period at 10,000 years. We have addressed comments specifically on the 10,000 year regulatory period in more detail in Section 3 of this document. Reflecting the discussion of our basis for the 10,000 years regulatory time frame, we concur on the comments (272, 567) that calculations into far distant time frames (like 100,000 years or more into the future) entail greater amounts of uncertainty as the time frame stretches outward. Recognizing these inherent uncertainties, we believe, however, that there is a useful purpose for requiring that long-term assessments be made. Using the 10,000 years time line as a measure for regulatory decision making about compliance is largely a policy-based decision, so that the time limit is not left to subjective debates over the exact time frame appropriate for any particular site (as a function of site-specific conditions like ground water travel time estimates). The projections of releases from the repository are also a function of the engineered barrier design [for the Yucca Mountain repository this is largely concerned with the waste package design and the use of drip shields (Chapter 7 of the BID)]. The repository design can be changed at any time until a license application for the repository is submitted, and therefore basing a regulatory limit on the expected performance of a specific design feature is not appropriate since it would be predicated on an assumed design and not on more fundamental considerations relating more directly to health protection, i.e., the degree of confidence that can be placed on long-term performance projections.

From a purely scientific perspective, there is no basis for assuming that performance calculations up to the 10,000 year point are inherently reliable whereas projections beyond that date are not. Therefore, EPA believes that the performance projections should be continued well beyond the 10,000 year period to examine the projected performance of the disposal system at the extremes of our confidence in these assessments. Since the confidence that can be placed in performance projections does not change between year 10,000 and 10,001 of the performance analyses, it appears prudent to extend the analyses into a longer time frame for the purpose of getting a more comprehensive picture of the site's anticipated performance. In requiring these long-term projections, we are asking whether, based on our understanding of the natural and engineered

barriers, a dramatic deterioration of the disposal system performance is to be expected, and if so when should it be expected. By extending repository performance projections into very long time frames, on the order of hundreds of thousands of years, the assessments should examine whether the total waste isolation system changes in a gradual manner or can degrade abruptly resulting in dramatic releases.

The NAS recommends that performance assessments be carried out to the time of estimated peak dose (NAS Report, p. 55), and EPA has incorporated this recommendation into the standard (§197.35). We note that DOE has performed assessments over a time frame of one million years (Viability Assessment, DOE/RW-0508, Docket A-95-12, Item V-A-5) – the time period that NAS estimates the geologic regime at the site is "geologically stable" – and we would expect that assessments over this time frame could be performed to support the licensing case to be presented by DOE. In addition, the newest repository design proposed by DOE, called EDA II (see Chapter 7 of the BID), features a very highly corrosion resistant waste package complemented by a drip shield to result in resistance to breaching from corrosion processes for tens of thousands of years (Yucca Mountain Economic Impact Analysis, Docket A-95-12, Item V-B-2). To assess the behavior of this design, performance assessments would have to be conducted on time frames of hundreds of thousands of years to assess potential releases from anticipated degradation processes.

Several comments (236, 398, 473, 593) focused specifically on the use of these post-10,000 year projections in the licensing process. One comment (593) states that EPA is inappropriately limiting NRC by stating that it "is not to use the additional analyses in determining compliance with proposed §197.20." This comment suggests that NRC should be permitted to use the post-10,000 year analyses in assessing compliance with the 10,000 year individual-protection standard if it believes such use to be appropriate. Other comments (473, 398) object that we have not provided sufficient guidance on the evaluation or use of these projections for licensing purposes. Still another comment (486) argues that the EPA standard must include additional licensing criteria to completely address the hazardous lifetime of the radionuclides beyond the 10,000 year regulatory period.

Specifically with respect to comments 236, 398, 473 and 593, the question of how to treat the performance projections in a licensing process, where a compliance decision has to be made, involves some additional considerations beyond just simply getting a more comprehensive picture of anticipated performance. As mentioned previously, the characteristics of the disposal site will change over long time periods in response to the natural processes active at the site, like seismicity in the area around Yucca Mountain that can affect ground water flow and structural integrity of the repository, or climatic variations that will affect the hydrologic setting at the site. The effects of these changes may be to improve performance of the repository, decrease performance, or the net effect of the changes might leave the performance essentially the same as that anticipated from current conditions. Different performance scenarios can be proposed with little concrete evidence favoring one over the other, and consequently, scientific consensus in a licensing process could be difficult to impossible to achieve. EPA has used language in the standard that establishes the requirement that very long-term performance projections be made for

the repository, and that they be reported in documents that will be included in the licensing process, and will be available for public review and comment (in the EIS that must accompany the license application). However, we have not specified how or whether the regulatory authority should use the information for licensing decision making. We anticipate that if these very long-range performance projections indicate that repository performance would degrade dramatically at some point in time, that this would become a concern in the licensing decision. If such a dramatic deterioration were projected to occur close to the regulatory time period it would be a more pressing concern for licensing decisions than if it were to occur many hundreds of thousands of years into the future (remembering that the uncertainty in performance projections increases with time). EPA has elected to leave the handling of the very long-term projections of performance as an implementation decision for the regulatory authority, but to impose the requirement that such analyses be performed and reported in the EIS. The degree of "weight" that should be given to these very long-term assessments we believe is an implementation decision that should be left to NRC to determine, by balancing the projected performance and the inherent uncertainties in these projections against the projected dose levels. As a result, while the post-10,000 year projections will not be used specifically to determine compliance with the 10,000 year individual-protection standard, they will constitute part of the full record available in the much broader context of facility licensing.

Another comment (557) suggests that requiring periodic updates of the performance assessment using more recent data would be more as a check on the original assumptions for the repository assessments. This approach is somewhat similar to that taken for WIPP, where DOE is required to demonstrate continued compliance every five years. As stated in NRC's proposed regulations (10 CFR part 63), the license application submitted in 2002 must be updated a number of times until the time when the application is made to amend the license to permit permanent closure of the repository. At these times the performance projections for the repository would presumably be re-evaluated using additional information and analyses made with newly obtained data (see proposed 10 CFR 63.22, 63.24, 63.33, 63.45, 63.51). In this way the performance projections will be re-evaluated over the period when the repository is constructed, wastes are emplaced and the repository is actively monitored prior to closure. It will be up to NRC to define the specifics of these periodic license amendments including the necessary updates of technical analyses, and what will constitute a satisfactory update. We believe the decisions of when and how to re-evaluate DOE's repository performance assessments within the execution of the licensing process is an implementation question that should be decided by NRC and therefore we must disagree with the suggestion that we establish within our standard explicit requirements for periodic updating of the repository performance projections. EPA believes that the standards we are establishing must be met for satisfactory compliance, but the process through which compliance is demonstrated is the responsibility of the implementing authority.

Comment 486 expresses the need for licensing criteria that address the longer-term waste isolation characteristics of the site after the engineered barrier system is assumed to have failed in its containment function. The criteria apparently being advocated are essentially subsystem performance criteria that would be applied as performance expectations for the natural barrier system. EPA notes that subsystem performance objectives, similar in intent to what the comment

proposed, are part of NRC's existing regulation for geologic disposal (10 CFR part 60). However, NAS did not recommend that subsystem performance requirements should be a part of our standard, and in commenting on NRC's 10 CFR part 60 it urged caution over the use of subsystem performance requirements. The NAS believes that subsystem requirements could lead to "suboptimal repository design" (NAS Report, p. 125). EPA believes that a total systems approach for assessing repository performance is the appropriate means to determine compliance with our standard and we agree with the NAS caution. We believe that subsystem requirements could serve as assurance measures to complement the total system limits contained in our standard; however, assurance measures are the responsibility of NRC to impose as part of its implementation responsibilities. We believe the question of subsystem performance requirements should be addressed by NRC in developing its implementing regulations for Yucca Mountain.

Issue D: Is it appropriate to require a consideration of changes in climate, geologic and hydrologic conditions over time in repository performance assessments?

1. It is appropriate to consider climate changes. Climate changes are very possible and exposure scenarios would change significantly.(15)

2. Seismic activity can cause changes in ground water pathways and the area is seismically active, and some recent events have occurred on faults previously considered inactive. (58, 106)

3. It is reasonable to vary natural conditions within reasonable bounds. (648)

4. We can be certain that there will be changes in climate, which may make the biosphere more temperate than today's dry regime. (164, 380) Such changes and conditions have been observed over the past 10,000 years and should be assumed to happen again. (366) Statements cited from the NAS report concerning future climate states being "Glacial states" are either too strong or not correct, and recent research by Ku, et. al. (1998) indicates that the majority of past climate in the Great Basin was not spent in the pluvial state. (581)

Response to Issue D:

Comments favored consideration of potential future variations in climatic and geologic conditions within reasonable bounds. Making projections of repository behavior over time periods of thousands of years involves addressing the subject of changing climatic and geologic conditions, since these conditions determine the geologic setting for the site over the regulatory time period and must be used in assessing how the repository's waste containment and isolation capabilities will perform. There are uncertainties in how these conditions will change over the long-term and some degree of speculation is inherent in estimating their potential variation. The NAS considered this subject and recommended that the effects of natural processes such as climate change, seismic and volcanic events could be reasonably bounded in performance assessments of the site (NAS Report, p. 9). EPA agrees with NAS, and we have required that the assessments used to project repository performance include the effects of these processes on the performance projections. In §197.36 of the final rule, we have given a probability limit for features, events,

and processes, or sequences of features, events, and processes, that would have to be included in the performance evaluations. This limit is intended to bound the range of the features, events, and processes to be included in order to eliminate highly speculative effects.

Most of the concern over potential climatic changes centered on the possibility that the region surrounding Yucca Mountain might become significantly cooler and wetter than it is today. Such a climate is generally considered less desirable for a geologic repository than a warm and dry environment because more water would be available to infiltrate the repository. One comment (380) suggests that DOE can bound the uncertainties to some extent by modeling a "hypothetical biosphere" that would provide more variation than assuming current conditions with "some constrained climate variation." Another comment (581) suggests that predictions of wetter future climates based on previous climate conditions may be incorrect since some recent research indicates past climates were not dominated by wetter conditions. The responsibility for projecting the bounds of future climatic variations and defending the projections in the licensing process belongs to DOE. EPA believes that it has addressed this situation by stating that DOE "must vary" climatic, geologic, and hydrologic assumptions to incorporate "reasonable scientific predictions" of changes over 10,000 years (§197.15). This assessment should also account for potential seismic activity. DOE's assessments of the Yucca Mountain repository performance in the DEIS and DOE/VA (Docket A-95-12, Items V-A-4 and V-A-5) have in fact considered a wide range of ground-water infiltration rates corresponding to a wetter climate.

Issue E: Is it appropriate to select and keep constant today's biosphere characteristics for assessing public health effects?

1. Changes in demographics, life styles, and technology observed historically make the assumption of fixed present conditions troubling. (31) Nevada has undergone extensive population increases that could affect water supplies if these continue in the future, as seems likely. (122, 132)

2. The possible increase in population density in areas adjacent to YM should be considered in framing biosphere characteristics. (71) The critical group cannot be defined independently from the biosphere - you need to assume either current site-specific attributes or a more stylized approach based on general characteristics. (511)

3. Equally troubling is the apparent inconsistency that exists between the way EPA treats the uncertainties of future human activities and those associated with future climatic and geologic conditions. Confronted with the uncertainties of future human activities in the area around Yucca Mountain, EPA concludes that current activities constitute the least arbitrary scenario to use in calculating potential human exposures. . . . When confronted with a similar type of uncertainty in the modeling of climatic and geologic conditions, EPA concludes that at a certain point the uncertainties of the analysis eliminate its credibility altogether, but fails to state why 10,000 years is the magic dividing line. (439)

4. Prohibiting consideration of societal changes for such long time periods leads to too strict a standard. (477)

5. It is reasonable to hold today's attributes constant. (463) Speculative data on future biosphere characteristics should be avoided. (569) It is speculative to suggest the manner of possible changes. (262, 648) The NAS recommended this position. (330)

6. Holding biosphere attributes constant will protect others (besides the RMEI, which should be defined as an age-weighted subsistence farmer at the edge of the repository) except for an intruder or people active at Franklin Lake Playa (a largely evaporative surface discharge area) in the far distant future. (381)

7. Can't use today's biosphere and cannot predict future populations near the site. (547)

8. NRC agrees in principle to fixing the biosphere characteristics, but specifying the biosphere characteristics is an NRC implementation function. (612)

Response to Issue E:

Comments on this subject varied widely. Some felt that the dynamic population growth in the Las Vegas and surrounding areas would argue against the use of static current conditions as unrealistic.
In support, another comment (547) asserted that future populations around the site could not be predicted and the current biosphere conditions could not be assumed for the standard. Some comments stated that technological advancements and societal changes should be given consideration, otherwise the standard would be too strict. Other comments reflected a belief that fixing biosphere parameters to current conditions is a reasonable approach in principle.

The NAS examined the question of the scientific feasibility of predicting future land uses, living styles and population distributions and concluded that there is no scientific basis to support making projections over the long-term (NAS Report, p. 10). Over a regulatory time period of 10,000 years, projections of population distribution and lifestyles are highly speculative and the use of such speculative assumptions for dose assessment calculations would only result in unresolvable controversy when used to make compliance decisions. EPA agrees with the NAS conclusion and has adopted a position in this standard that avoids speculative assumptions about biosphere changes over the compliance period by assuming current conditions – which can be defined reliably. While it is certain the current conditions will change, EPA cannot, with certainty, project the nature or character of such changes. Thus, any speculative assumptions concerning possible future states differing from current conditions would be arbitrary.

By developing a standard that assumes current biosphere conditions, including such aspects as current risk estimates for health effects due to radiation exposure, EPA has built in a measure of conservatism. If our standard provides an acceptable level of protection today, it is not unreasonable to presume that future advances in medical diagnosis and treatment would reduce

risks to future, potentially exposed individuals. One comment (477) suggests exactly this possibility to support a position that our standard is too strict. However, this comment then goes on to say, "Should, on the other hand, there be an intervening collapse of historical and technological continuity, doses of 15 mrem would be irrelevantly unimportant compared to the disasters that caused the collapse." The fact that the comment offers no basis for supporting either of these extremes precisely illustrates the dilemma in forecasting the characteristics of future societies and the necessity to assume present conditions will persist into the future. Any other assumption leads to potentially unlimited speculative scenarios to be put forward in a licensing process.

Another comment (439) accuses EPA of inconsistency in its handling of uncertainties related to human activities and those related to climatic and geologic conditions. In the commenter's view, holding human activity at current levels is reasonable, if not optimal. According to this comment, however, EPA provides insufficient justification for stating that at a certain point, uncertainties in climatic and geologic changes overwhelm the ability to project exposures. More specifically, the comment objects to our drawing a "magic dividing line" at 10,000 years, rather than requiring compliance to the time of peak dose. It is suggested that we should define a bounding scenario for these uncertainties, and that this approach would be consistent with the NAS recommendation.

In assessing the NAS recommendation, EPA has considered a number of factors, including policy issues not specifically addressed by NAS. NAS acknowledged that policy considerations would play a legitimate role in setting a compliance period. Section 3 of this document describes in detail the reasoning we have used to set the regulatory time frame at 10,000 years. Contrary to the comment's assertion, we do not assign a "magic" significance to 10,000 years. Performance calculations are not highly reliable slightly before the 10,000 year period and become highly unreliable slightly thereafter. Clearly we believe that calculations beyond 10,000 years have value, or we would not have required DOE to include them in its EIS. However, we also believe that over the very long time periods leading up to the peak dose and beyond, the uncertainties in projecting climatic and geologic conditions become extremely difficult to reliably predict and a technical consensus about their effects on projected performance in a licensing process would be very difficult, or perhaps impossible, to achieve. This is one of the major reasons that the 10,000 year time frame was originally selected in the generic standard for land disposal of the types of waste intended for the Yucca Mountain repository (40 CFR part 191).

One comment from NRC (612) agreed in principle with fixing biosphere characteristics, but stated that it should be NRC's responsibility. EPA has not in fact fixed all of the relevant characteristics of the biosphere in the standard, leaving considerable flexibility to DOE and NRC to more specifically define the biosphere characteristics that will control dose assessment evaluations. We have affirmed the principle that present day conditions should be assumed, and we have only specified a few details of the biosphere in the context of defining the RMEI in sufficient detail that biosphere analyses resulting in dose projections can be framed as we intend in the standard. EPA has specified a fixed amount of drinking water consumption and that lifestyle and dietary patterns for the RMEI be representative of the population in the Amargosa Valley area (see Section 4 of

this document for more discussion of the RMEI). The details on these aspects are left to DOE and NRC to define during the licensing process. We feel that we have been only specific enough to provide a context for implementation. The task of precisely defining all the relevant biosphere characteristics for use in dose assessments and assessing dose estimates as a function of the variation in these characteristics is, we believe, the responsibility of DOE and NRC to resolve in the licensing process.

Issue F: Is it appropriate to expect that the risks to future generations should be no greater than risks judged acceptable today?

1. Risks should be limited to what is acceptable today. (225) The risks should be communicated to future generations. (170) This idea is embodied in the Nuclear Waste Policy Act. (268) Radiological criteria should be considered as indicators of health detriment rather than measurements. (517) Expected risk calculations should recognize that technological advances will in reality lower future risks. (527) Risk estimates should be re-assessable on a scale of 50-300 yrs. (571) It makes sense to rely on dose/risk projections only for compliance periods within which the assumptions used to generate those projections remain reasonable. (618)

2. Compliance assessments will incorporate conservatisms to compensate for uncertainties, which will effectively lower actual risks to future populations. (231)

3. Yes. However, future risk research will suggests that the effects of low-dose radiation are lower than current projections.(331)

4. Dose conversion factors used to calculate risk to future generations should reflect the greater uncertainty in dose projections compared to calculating current risk. (388) Dose/risk conversion factors may be different than what's assumed today. (468)

5. Has a war scenario or sabotage/terrorism been considered? (539)

6. Inter-generational equity is appropriate, but the individual protection standard is adequate protection. (654)

7. The standard should be the most conservative considering the great uncertainties over 10,000 years, not less conservative because of the uncertainty. (10)

8. The "risks judged acceptable today" by the nuclear power industry and the DOE and EPA are not acceptable to many of those who are, even currently, at the highest risk. (372)

Response to Issue F:

Comments on the issue of potential risk to future generations considered a wide range of relevant factors. Some comments stressed the need to communicate risks to future generations and periodically reassess the risks, while others stress that risks will in reality decrease in the future as a result of technological advancement or increased understanding of radiation effects. Some comments recommended that risk/dose conversion factors consider uncertainty and may be different in the future. Other comments expressed opinions that the assessments performed contained enough compensating factors to make up for uncertainties, that inter-generational equity is appropriate, that risks should be limited to today's acceptable levels, and that the individual protection standard was sufficient for the purpose. One comment inquired about whether war, sabotage or terrorism scenarios had been considered.

The intent behind geologic disposal of nuclear wastes is that the generation enjoying the benefits of nuclear energy should bear the burden of disposal efforts for the waste products and not pass on the liabilities to future generations. Consistent with this aim, EPA believes it is appropriate that the risks from nuclear waste disposal should not be greater to future generations than the level considered acceptable today. Section 111 (a)(7) of the NWPA embodies this principle: "...appropriate precautions must be taken to ensure that such waste and spent fuel do not adversely affect the public health and safety and the environment for this and future generations," (NWPA, Pub. L. No. 97-425, 96 U.S. Stat. 2201, 2207). This position is also a foundation of international practice, as stated by the IAEA in its "Principles of Radioactive Waste Management" (IAEA Safety Series No. 111-F, 1995, Docket A-95-12, Item V-A-10).

EPA's standard addresses this issue by requiring the projected performance of the geologic repository to meet exposure limits considered acceptably low, for a period of at least 10,000 years. The 15 mrem/yr dose limit set in the generic standard for land disposal of the types of waste intended for the Yucca Mountain repository, in 40 CFR part 191, reflects a societal decision on acceptable risk, resulting from the public rulemaking process used to establish that standard (although, as comment 372 points out, "societal decisions" may not be to the liking of each individual member of that society). This limit was also used in the certification of the WIPP geologic disposal facility in New Mexico. EPA sees no reason to believe that the same level of protection, or alternatively stated, the same level of risk, should not be applied to the Yucca Mountain geologic repository. Through the public rulemaking process we are establishing an acceptable risk level for the Yucca Mountain repository performance requirements. This standard establishes the same level of protection as our previous rulemakings for deep geologic disposal – an individual exposure limit of 15 mrem/yr to the RMEI at the compliance point for a period of 10,000 years. Our final rule also includes standards to protect ground water resources downgradient from the repository from unacceptable contamination for the same time period. The standards will be implemented by the NRC through a licensing process in which DOE will have to demonstrate that the geologic disposal facility at Yucca Mountain will provide the performance necessary to comply with those standards.

In addition, the NAS recommendations on technical bases for the Yucca Mountain standard proposed an exposure level between 2 and 20 mrem/yr as the range of potentially acceptable exposures (NAS Report, p. 5). The exposure level EPA set in this standard falls within that range and is consistent with the existing regulations and the WIPP disposal facility application of the 40 CFR part 191 standard.

A theme frequently repeated in the NAS recommendations is that speculation about societal conditions, technological advancement, or human actions cannot be defended scientifically and therefore considerable caution is needed in making projections into the distant future. EPA assumes that if the disposal facility can demonstrate compliance with the level of confidence considered adequate today, future generations will also be protected. We believe that a 10,000 year regulatory compliance period is sufficiently long to assure inter-generational equity for the potential risks from a geologic repository (see other comment responses dealing with the regulatory time period in Section 3 of this document). Improvements in technology, particularly medical diagnosis and treatment, indicate that future risks should be lower than current risk estimates ("likely to reduce the consequences of exposure to radiation"). One comment (331) stated that further research will show that the risks of low-doses of radiation have been over-estimated. If this suggestion is eventually confirmed, our standard would still be protective, although perhaps more conservatively than currently thought.

Comments 388 and 468 expressed concern that uncertainties in long-term future dose projections should be reflected in the dose conversion factors used for performance assessments, and that these conversion factors may be different in the future than the values assumed today. Comment 618 cautioned that EPA's standard should be viewed as an indicator of repository performance, rather than having a specific correlation to expected health effects, because such correlations are unreliable after a few hundred years. Other comments reflected somewhat differing viewpoints on the effects of uncertainties (apart from dose conversion factors). Comment 231 suggested that future generations would actually be more protected than our standard requires because DOE would introduce considerable conservatism into its long-term projections to account for uncertainty. Comment 10 took the position that our individual-protection standard should be more stringent (i.e., lower) precisely because of the uncertainties involved in projecting long-term exposures. Consideration of uncertainties is an integral part of the decision that the site does or does not meet the compliance requirements, and it is the responsibility of the implementing authority to determine if the uncertainties have been adequately assessed. We have not specified the details of how the uncertainty assessments will be done, preferring rather to include a concept first put forward in our generic standard – the concept of reasonable expectation (see 40 CFR 191.15). Section 197.14 of our final rule also describes the intent of the reasonable expectation as recognizing that absolute proof, in the ordinary sense of the word, is not attainable for repository performance projections over the long time periods considered. Inherent in this approach is a burden on the implementing authority to consider the uncertainties inherent in the features, events, and processes involved. It is the responsibility of the implementing authority (in this case NRC) to develop the detailed requirements for examining the uncertainties involved in projecting repository performance. A more detailed discussion of reasonable expectation is located in Section 2 of this document.

Comment 571 suggested that the repository risk estimates be reassessed on a scale of 50-300 years, essentially saying that the compliance decision be reassessed periodically in some formalized way (analogous to DOE's WIPP certification, which must be re-evaluated every five years). Our standard puts forth the exposure limits and ground-water contamination limits considered acceptable; however, the mechanisms for making the final compliance decision and approving the disposal site for operation lie with the implementing authority (the NRC). Currently, DOE's plans for the operation of the repository indicate that it will be actively monitored for a period of about one hundred years after operations begin, at which time a license amendment would be filed with NRC to allow permanent closure of the repository. This long monitoring period would allow the risks from the projected repository performance to be reassessed at least once in the context of the licensing process before the repository is closed. Any decisions about future reassessments beyond that time would be an implementation decision that we would defer to NRC's discretion. We note that NRC has proposed a performance confirmation program to verify the data, assumptions, and analyses used to demonstrate compliance with our standard until permanent closure of the repository [proposed 10 CFR 63.102(m)].

Comment 539 asked if EPA had considered war, terrorism or sabotage scenarios in developing the protection requirements. In the context of making its recommendations, NAS concluded that there was no scientific basis for predicting the probability of deliberate intrusion into the repository for malicious purposes (NAS Report, p. 106). We agree with that opinion and have not considered these scenarios in developing the standards, which focus on the ability of the repository to isolate the waste from the environment (see also the comments on the human intrusion standard in Section 5 of this document).

On the question of communicating risks to future generations, the generic 40 CFR part 191 standard requires that institutional controls be required as an assurance measure to achieve that purpose. Institutional controls are of two types: active controls which require a deliberate dedication of resources to limit access to the repository site for a period of time, such as erecting and maintaining fences; and passive controls designed to convey the nature and risks of the repository contents to future generations, such as erecting monuments, establishing records in public archives, etc. EPA has not included requirements for these kinds of institutional controls because the text of our generic regulation states that these measures are not necessary if the implementing agency (NRC), includes them in its regulations. We anticipate that requirements for institutional controls will be incorporated into the implementing regulations developed by NRC for the Yucca Mountain repository (10 CFR part 63), as they are included in NRC's proposed rule. It then would become the responsibility of NRC to judge the effectiveness of DOE's proposed institutional controls for communicating the risks of the repository to future generations.

Issue G: The fragility of arid land should be considered in this standard.

1. I don't think – particularly for people in the east – that arid lands are wastelands that can well be sacrificed to this damaging or potentially damaging, if you prefer, utilization.. Arid lands are along with cold lands of the world, really the most fragile of all ecosystems. (37)

Response to Issue G:

The performance standards in this rule are not based on climate conditions. The limits are based on protective levels of radiation exposure and ground-water contamination that would be appropriate for geologic disposal in any climatic regime.

Issue H: Insufficient site characterization has been completed for Yucca Mountain.

1. We are still concerned about the lack of rigor that is currently being applied in the site characterization program for Yucca Mountain. The Yucca Mountain site is extremely complex geologically and hydrographically. There has been too much emphasis however placed on models and expert elicitation processes rather than the development of comprehensive information and data. (114)

Response to Issue H:

EPA agrees that Yucca Mountain is a very complex site. For this reason, we have included requirements and direction in the rule that deal with the questions of the features, events, and processes to be considered in assessing the site's projected performance (§197.15 and §197.36), and for the level of understanding necessary for presenting an acceptable demonstration of compliance in licensing, i.e., our explanation of the "reasonable expectation" term used in our standard (§197.14). It is the responsibility of DOE to characterize the site to a degree adequate to support the performance case presented in the license application to NRC. It is NRC's responsibility to evaluate DOE's performance case and the data base and understanding underlying it, including the uncertainty involved in characterizing the site and in projecting the performance of the site's natural and engineered barriers. The degree to which elicited information from experts and data collected in field studies are used in making performance projections for the site is an implementation issue that we believe is the responsibility of NRC to exercise in the course of its licensing efforts.

Issue I: Yucca Mountain is a geologically uncertain location for radioactive waste.

1. The cinder cones visible from the top of Yucca Mountain makes it clear that Yucca Mountain is indeed a geologically uncertain location for radioactive waste. (34)

2. This hill was not supposed to have water in it. It was one of the original criteria. Well, the guys who are working on the site characterization project found water in the hill. This was supposed to be a nice solid hill, no faults. They found faults. There seems to be a continual changing of the requirements of successful characterization to fit the hill. That doesn't sit well.

And this area is characterized as rarely having earthquakes. Well, we had a good one the other day. (65)

Response to Issue I:

EPA recognizes that uncertainties in projecting the site's performance are important components in evaluating the site's potential performance, and we have reflected this understanding by the requirements and direction given in Sections 197.15 and 197.36 of the standards. The standards require the assessment of features, events, and processes expected to be active and to have effects on the performance of the natural and engineered barriers during the regulatory period (§197.36). To identify potentially important features, events, and processes, the geologic record at the site is a prime source of information for determining the probabilities of relevant features, events, and processes, and potentially disruptive events such as the volcanic events and earthquakes mentioned in the comments. The potential for these features, events, and processes and their effects on waste containment and isolation are to be included in the performance projections used in the license application to demonstrate that the site will meet the requirements of the standards. The DOE is responsible for developing the information to support the performance assessments used in licensing, including the estimates of uncertainty in that information and its evaluation. The NRC is responsible for determining the acceptability of the information and assessments presented by DOE and for making the final decision on the site's compliance with the standards.

As explained in discussions on the rationales for the standards in the preamble to the rule and this comment response document, EPA's standards address the total system performance of the Yucca Mountain disposal system – not specific characteristics of the site such as seismicity or hydrology. The individual exposure and ground-water protection limits are not based on characteristics of the site. Our direction and responsibility for developing the Yucca Mountain standard is to establish protective standards for the Yucca Mountain disposal system in total. It is the responsibility of DOE to adequately characterize the site, develop an engineered barrier system for the site, and present a performance case for licensing. It is NRC's responsibility to evaluate the performance projections and their uncertainty, and make the final decision on compliance with the standards. The characteristics of the site mentioned in this comment will be part of the uncertainty considerations NRC will have to evaluate during licensing.

Issue J: Disagree with EPA that the corrosion rates of the canister components may be quantified with a higher degree of accuracy and precision. (289, 544, 582)

Response to Issue J:

These comments express disagreement with the conditional statement in the preamble to the proposed rule indicating that corrosion rates may be highly quantified. This statement was made in the context of discussions on the meaning of reasonable expectation and the framing of performance scenarios. The comments focus on the extrapolation of laboratory corrosion testing data for performance estimates of the waste container over the regulatory time frame. It was not EPA's intention to imply that there is no uncertainty in the extrapolation of laboratory-measured

corrosion rates to long time frames. We agree there is uncertainty in such extrapolations, but this was not the context of the statement in the preamble text. Rather, the context of the text was the comparison of data and assumptions used to construct and analyze performance scenarios. Some parameters, such as corrosion rates of metal components, would be derived from data bases of laboratory experiments, which can be conducted repeatedly and with a high degree of precision and accuracy for the system being measured, i.e., short-term corrosion rates under laboratory conditions. Other parameters used in repository performance assessments would be based on less easily obtained data, such as the rates of ground water flow into waste emplacement drifts. Water inflow data, in contrast to well-defined laboratory studies, are derived from measurements of other parameters that are uncertain, making the estimates of ground water seepage a function of the uncertainty in the measured parameters and models used to estimate it. The intent of the preamble discussion was to illustrate that the data used in performance assessments can have varying degrees of uncertainty inherent in them and that these uncertainties should be recognized and considered in the assessments, rather than omitted from the assessments or assumed to be at their most extreme values merely to simplify the analyses.

Comment 582 also mentioned that natural system behavior can be based on evidence in the geologic record as opposed to engineered barrier projections based on laboratory testing. The contrast illustrates an important point about uncertainty and repository performance projections. The geologic record provides evidence for the operation of features, events, and processes and their effects over very long time frames – tens, to hundreds of thousands, to millions of years. Extrapolating data from the geologic record to annual rates used in repository assessments involves the uncertainty of going from the long time frame to the small. The extrapolation of short-term laboratory data to the thousands to tens of thousands of years necessary for compliance assessments involves the reverse process; going from short times (months to years) to comparatively long time frames. Both extrapolations are inherently uncertain, and these uncertainties should be fully understood and evaluated, as we point out in our discussions on the reasonable expectation concept (see Section 2 of this document).

Issue K: It is not necessary for EPA to establish assurance requirements. (313, 605)

1. This is an implementation issue that should be left up to NRC. (248, 652)

2. Assurance requirements are more appropriate to implementation than standard setting and are already included in NRC's proposed Part 63 and DOE's proposed 963. (576)

Issue L: EPA's standard should include assurance requirements.

1. We support the use of qualitative *assurance requirements* to maximize confidence in the quantitative standards. We are also in favor of these to increase confidence in the performance of the repository. (349)

Response to Issues K through L:

In the preamble to our proposed standards (64 *FR* 46998), EPA requested comment on whether it is appropriate for EPA to establish assurance requirements in this final rule and if so, what those requirements should be. We recognize that, because of the highly extended regulatory time frame applicable to Yucca Mountain, it is desirable to consider qualitative elements that may reduce some of the uncertainties associated with projecting the effects from releases from radioactive wastes over long periods.

Our generally applicable standards for the disposal of SNF, HLW, and TRU wastes (40 CFR part 191, 58 *FR* 66402, December 20, 1993; 50 *FR* 38073 and 38078, September 19, 1985) require the consideration of assurance requirements. The assurance requirements in 40 CFR part 191, however, do not apply to facilities that NRC regulates, like Yucca Mountain. However, because the EnPA mandates that EPA set site-specific standards for Yucca Mountain, we believe that we have the authority to include assurance requirements in this rule. Based on the public comments on the proposal and the fact that NRC's proposed licensing criteria (see proposed 10 CFR 63.102, 63.111, and 63.113; 64 *FR* 8640, 8674-8677, February 22, 1999) contain requirements for multiple barriers, institutional controls, monitoring, and the retrievability of waste from Yucca Mountain, we believe that it is not necessary for us to include similar requirements in this rule. We encourage NRC to include the assurance requirements, or requirements similar to those in 40 CFR part 191, in its final licensing criteria for Yucca Mountain.

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